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In re Application of:) Art Unit: 1654
JANSSON, John-Olov) Examiner: LUKTON, D.
Appl. No.: 10/530,866) Washington, D.C.
Filed: April 11, 2005) October 23, 2006
For: USE OF GHRELIN FOR TREATING MALNUTRITION) Docket No.: JANSSON=7
IN GASTRECTOMIZED) Confirmation No.: 2241

ELECTION WITH TRAVERSE

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Sir:

- In response to the restriction mailed September 21,
 Applicants elect group I with traverse.
- 2. The instant application is the national stage of a PCT application, so PCT unity rules apply.

The Examiner concedes that inventions II and I are related as combination and subcombination. That is correct.

The Examiner cites the MPEP 806.05(c) standard as to whether combination and subcombination are distinct. That provision applies only in domestic practice.

We respectfully direct the Examiner's attention to the PCT Administrative Instructions, Annex B, paragraph (c)(1): "no problem arises in the case of a combination/subcombination situation where the subcombination avoids the prior art and the combination includes all the features of the subcombination.

Moreover, the Examiner analysis under 806.05(c) is incomplete. He doesn't show that 806.05(c)(1) is met, i.e., that the combination as claimed does not require the particulars of

the subcombination as claimed (the ghrelin) for patentability. I find it hard to believe that the presence of "another stomach-derived factor" (claim 18) is sufficient for patentability. The international rule is that if the subcombination is patentable, no unity problem is created by a dependent claim to the combination.

- 3. In response to the five species restrictions set forth on page 4, we make the following species elections:
 - a) we elect "(i) one and only one of G1-G4 is required";
 - b) we elect ghrelin (native human ghrelin);
 - c) we elect "(ii) a composition which comprises a peptide is administered";
 - d) we elect a composition consisting of ghrelin and water;
 - e) we elect oral administration.

Technically speaking, in international practice, a species restriction is proper only if the Examiner makes a <u>prima facie</u> showing that generic claims are not allowable (<u>a posteriori</u> lack of unity). Whereas in domestic practice, the Examiner can restrict prospectively, to limit the field of search. The species restrictions are therefore procedurally improper.

In any event, we traverse the restrictions (a)-(e) on the ground that generic claims are allowable, i.e., the limitations of the claims supply a unifying special technical feature.

4. In addition, in species restriction (c), the peptide (i) has a subcombination/combination relationship to the composition (ii). Hence, the Examiner must also address why this relationship doesn't create unity.

A similar issue exists for restriction (a). One of G1-G4 is a subcombination of two of G1-G4, and so forth.

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4.1. All claims read on the elected species (i) response to restriction (a).

4.2. All claims except 2-10 read on the elected ghrelin of restriction (b) (this assumes that the "modified amino acid" language of claim 2 excludes native human ghrelin).

4.3. All claims read on the elected composition responsive to requirement (c).

4.4. All claims except 15 read on the elected ghrelin-water combination ("saline" also contains salt), per (d).

4.5. All claims except 27 read on the elected oral administration (assuming that "a form suitable for subcutaneous administration" is inherently unsuitable for oral administration), per (e).

Thus, if the group restriction and all species restrictions are maintained, the examined claims will be 1 and 14.

Respectfully submitted,

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